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## REMARKS

This Amendment is responsive to the Office Action dated August 4, 2006. Applicant has amended claims 1, 6, 9, 11-13, 18, 21, 23, 26 and 30, and added claims 32 and 33. Claims 1-24 and 26-33 are pending.

### Claim Objections

The Office Action objected to claim 11 under 37 CFR § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of independent claim 1. Independent claim 1 recites housings that are at least partially encapsulated, and separately encapsulated, by an overmold. As amended, claim 11 recites that the overmold completely encapsulates each of the housings. The Office Action interpreted the phrase "separately encapsulated" in claim 1 as meaning that the overmold completely encapsulates each of the modules, i.e., as requiring the same scope that as the limitation recited in claim 11.

Applicant respectfully disagrees with the interpretation of the phrase "separately encapsulated. Housings may be separately encapsulated without being completely encapsulated. For example, Applicant points to paragraph [0069] and FIG. 10B of Applicant's disclosure as describing separately and partially encapsulated modules.

Claim 1 recites housings that are separately encapsulated and at least partially encapsulated, rather than completely encapsulated. Applicant's claim 11 further requires that the overmold of claim 1 "completely encapsulates each of the modules." Applicant submits that claim 11 further limits the subject matter of amended claim 1 and requests withdrawal of the objection.

### Claim Rejection Under 35 U.S.C. § 112

The Office Action rejected claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action stated that the limitations of claim 12 appear to be contradictory to the limitation previously set forth in claim 1. More particularly, the Office Action interpreted the phrase "separately encapsulated" in claim 1 as meaning the

overmold completely encapsulates each of the modules, which would be contrary to the recitation in amended claim 12 that the overmold does not encapsulate a portion of each of the housings.

As described previously in this Amendment, modules may be separately encapsulated without being completely encapsulated. For example, paragraph [0069] and FIG. 10B of Applicant's disclosure describe separately and partially encapsulated modules. Claim 1 recites housings that are separately encapsulated and at least partially encapsulated, rather than completely encapsulated. Claim 12 further limits and is consistent the recitation of claim 1 by stating that "the overmold does not encapsulate a portion of each of the modules that is proximate to a cranium of a patient when the implantable medical device is implanted on the cranium." Applicant submits that claim 12 particularly points out and distinctly claims the subject matter which Applicant regards as the invention. Withdrawal of the rejection is requested.

**Claim Rejection Under 35 U.S.C. § 101**

In the Office Action, the Examiner rejected claims 1, 6, 9, 12-13, 18, 21, 23, 26 and 30 under 35 U.S.C. § 101 as being directed to non-statutory subject matter for reciting structures in relation to the body. Applicant has amended claims 1, 6, 9, 12-13, 18, 21, 23, 26 and 30 for purposes of clarification. Applicant submits that claims, as amended, recite statutory subject matter, as required by 35 U.S.C. § 101.

**Claim Rejection Under 35 U.S.C. § 102**

The Office Action rejected claims 1-6, 10-11, 13, 18-19 and 28-29 under 35 U.S.C. § 102(b) as being anticipated by Leysieffer et al. (U.S. Patent No. 6,131,581, herein referred to as Leysieffer). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Leysieffer fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Leysieffer fails to teach or suggest "an implantable medical device comprising a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of housings, and an overmold that at least partially encapsulates each of the

housings, wherein the housings are horizontally distributed at respective locations of the overmold and separately encapsulated by the overmold, and wherein the overmold is formed such that a surface of the overmold is concave along at least one axis prior to manipulation of the implantable medical device such that the surface is adapted to be implanted proximate to the cranium," as recited by Applicant's independent claim 1, as amended.

In support of the rejection of claim 1, the Examiner characterized Seebeck elements (also referred to as modules) 20 of Leysieffer as interconnected modules which each comprise a housing. Modules 20 of Leysieffer contain two legs of material having different electrical conductivity, both connected to hot pole 15 at one end and cold pole 16 at an opposite end. The legs, which serve to create an electrical output, may be composed of titanium and are connected to each other by thermally insulating composite element 23.[1]

Applicant's disclosure, for example at paragraphs [0004] and [0027], describes a housing that houses components of an implantable medical device, and an implantable medical device with components that are distributed amongst modules rather than included within a single housing. In Leysieffer's disclosure, each one of modules 20 does not comprise a housing, as required by Applicant's claim 1. Modules 20 are not housings because they do not "house" anything. Instead, each module is an electrical component without a housing. In support of the rejection of claim 1, the Office Action incorrectly asserted that each one of modules 20 comprises a module and housing.

Leysieffer describes modules 20 as miniaturized microelectronic components. Miniaturized Seebeck elements may be manufactured by using processes of microsystem engineering and more than 100,000 may be needed to produce enough power to continuously operate implants such as hearing devices.[2] Leysieffer does not suggest that modules 20 each comprise a housing. Instead, each module is a microelectronic component without a housing. Modules 20 do not have housings that house components of a medical device, and Leysieffer does not suggest including housings on modules 20.

In fact, since modules 20 serve to aid in the process of generating power using the Seebeck effect, it may be counterproductive to house modules 20 within housings. Modules 20

[1] Leysieffer, column 4, lines 4-41.
[2] Leysieffer, column 4, lines 53-65.

are thermally coupled to hot pole 15 and cold pole 16 in order to convert thermal energy into electrical power. In order to produce power, modules 20 must be exposed to the temperature difference between hot pole 15 and cold pole 16. Placing modules 20 within housings may limit the thermal coupling necessary for modules 20 to create power. For at least these reasons, Leysieffer fails to disclose or suggest all of the requirements of Applicant's claim 1.

With respect to Applicant's claim 13, Leysieffer fails to disclose or suggest that a housing of each of the modules comprises a surface that is adapted to be implanted proximate to a cranium, and the surface of the housing of at least one of the modules is concave along at least one axis. The Office Action cited FIG. 3 of Leysieffer as illustrating the requirements of Applicant's claim 13.

As described previously in this Amendment, Leysieffer fails to disclose or suggest a module comprising a housing, as required by claim 13. Additionally, the surfaces of the modules 20 proximate to skull 14 in Leysieffer's FIG. 3 are not concave. In fact, all of the surfaces of modules 20 are depicted as straight surfaces. Although the overall shape of the thermoelectric energy converter is concave and a series of modules in combination with overmold 23 form a concave surface, each individual module is made up of straight surfaces. When each module is considered individually, none of the modules have a concave surface proximate to skull 14. Additionally, Leysieffer does not disclose or suggest making a surface of a module concave. For at least these reasons, Leysieffer fails to disclose or suggest all of the requirements of Applicant's claim 13.

Similarly, with respect to claim 18, Leysieffer fails to disclose a housing that is concave such that the surface is adapted to conform substantially to the cranium. Leysieffer fails to disclose or suggest a module with a housing and, instead, describes an electrical component without a housing. Leysieffer also fails to disclose or suggest a module with a concave surface. Furthermore, since Leysieffer fails to disclose or suggest a module with a concave surface, Leysieffer also fails to disclose or suggest a module with a concave surface adapted to conform substantially to the cranium.

Leysieffer also fails to disclose or suggest at least two metallic housings, as required by Applicant's claim 28, and at least two housings that are hermetic and formed of titanium or stainless steel, as required by Applicant's claim 29. In support of the rejection of claims 28 and

29, the Examiner cited column 4, lines 26-41 of Leysieffer as teaching that the housings of modules 20 may comprise metals such as titanium and titanium alloys. However, this passage describes that legs 21 and 22 of a module may be made of metals such as titanium and titanium alloys. Leysieffer does not disclose or suggest that modules 20 each comprise a housing and certainly does not disclose or suggest that the legs of a module comprise a housing. For at least these reasons, Leysieffer does not disclose or suggest that a housing may be made out of metals such as titanium or titanium alloys.

The Examiner also stated that it is inherent that the housings of the modules are hermetic, otherwise the semiconductor properties of the modules or the energy generation properties would be compromised. However, Leysieffer states, "the hermetic gas tightness which is otherwise required in such active implants that contain microelectronics is not absolutely necessary in this application, especially if small volumetric portions of water vapor do not damage the individual modules 20 internally over the long term and if the material does not introduce toxic substances into the body."[3] Leysieffer suggests that internal portions of modules 20 may be exposed to water vapor if the thermoelectric energy converter is not hermetically sealed, which suggests that modules 20 are not covered with hermetically sealed housings. Additionally, Leysieffer states that hermetic gas tightness is not absolutely necessary in the application of the thermoelectric energy converter and provides no disclosure or suggestion indicating that hermetic housings may be included on modules 20.

Leysieffer fails to disclose each and every limitation set forth in claims 1, 13, 18, 28 and 29. Claims 2-6, 10-11, 13 and 18-19 are dependent upon claim 1, and are also in condition for allowance. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-6, 10-11, 13, 18-19 and 28-29 under 35 U.S.C. §°102(b). Withdrawal of this rejection is requested.

[3] Leysieffer, column 5, lines 8-15.

**Claim Rejection Under 35 U.S.C. § 102/103**

The Office Action rejected claims 14 and 22 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Leysieffer. Applicant respectfully traverses the rejection. Leysieffer fails to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Applicant's claim 14 recites "at least one of the modules comprises a control module that includes control electronics, and the surface of the housing of the control module is concave along two axes." In support of the rejection of claims 14, the Examiner pointed to the block diagram illustrated in FIG. 9, which diagrams energy converter 10, energy storage 27, control unit 28, and active implant 26 integrated in a single implant 35. Additionally, the Examiner stated that it is inherent or at least obvious that in this embodiment element 23 and the individual modules would be shaped in a dome, since Leysieffer teaches that it is desirable for implants located in the mastoid region to be dome shaped.

As described previously in this Amendment, the Examiner characterized microelectronic Seebeck elements as being modules within the meaning of claim 14. However, modules 20 do not comprise housings and do not have a concave surface, as required by claim 14. As described previously in this Amendment, modules 20 are made up of straight surfaces. Leysieffer fails to disclose or suggest a module with a concave surface, and certainly does not disclose or suggest a module with a surface that is concave along at least two axes.

Further, modules 20 function to produce useable energy; not to house control electronics. Modules 20 are described as miniaturized semiconductive elements. Leysieffer does not disclose or suggest that modules 20 include control electronics.

Additionally, modules 20 serve to convert thermal energy into electric power within thermoelectric energy converter 10. In FIG. 9, which was cited by the Examiner, thermoelectric energy converter 10 and control unit 28 are two separate components. Including power generating modules 20 within control unit 28 would serve no purpose in the device described Leysieffer and, in any event, is not remotely suggested by Leysieffer. For at least these reasons, Leysieffer fails to disclose or suggest the requirements of Applicant's claim 14.

Applicant's claim 22 recites "a therapy delivery circuit to deliver stimulation to a brain of the patient and control electronics to control the delivery of stimulation by the therapy delivery circuit, wherein the therapy delivery circuit and control electronics are located within one of the modules." As described previously with respect to claim 14, Leysieffer fails to disclose or suggest a module that includes control electronics.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 14 and 22 under 35 U.S.C. §§ 102(b) or 103(a). Withdrawal of this rejection is requested.

**Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 7-9, 19-21 and 30-31 under 35 U.S.C. § 103(a) as being unpatentable over Leysieffer; and rejected claims 23-24 and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over Muto et al. (U.S. Patent No. 4,094,321, herein referred to as Muto). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that neither Leysieffer nor Muto provides any teaching sufficient to overcome the basic deficiencies of Leysieffer described with respect to Applicant's amended independent claim 1. Claims 7-9 and 19-21 are dependent upon claim 1 and are also in condition for allowance.

Additionally, Applicant's claim 19 requires that a surface of the housing is concave such that the surface conforms substantially to an arc, and a radius of the arc is within a range from 4.5 to 9.5 centimeters. Claim 20 further requires that the radius of the arc is approximately equal to 7 centimeters. Additionally, claim 21 requires that a second surface of the housing that is adapted to be implanted distal from the cranium conforms to the arc.

As described previously in this Amendment, the surfaces of the modules 20 proximate to skull 14 are not concave. In fact, all of the surfaces of modules 20 are depicted, for example see FIG. 3 of Leysieffer, as straight surfaces. Although the overall shape of the thermoelectric energy converter is concave and a series of modules in combination with element 23 form a

concave surface, each individual module is made up of straight surfaces. When each module is considered individually, none of the modules have a concave surface proximate to skull 14. Since Leysieffer fails to disclose or suggest a housing with a concave surface, Leysieffer also fails to disclose or suggest the requirements of Applicant's claim 19-21. For example, Leysieffer fails to disclose or suggest a surface of a housing that conforms substantially to an arc with a radius in the range of 4.5 to 9.5 centimeters.

With respect to claim 30, Leysieffer fails to disclose or suggest "an implantable medical device comprising a plurality of interconnected modules, each of the modules comprising a respective one of a plurality of metallic housings, and a flexible overmold that at least partially encapsulates each of the housings, wherein the overmold is formed such that a surface of the overmold that is adapted to be implanted proximate to a cranium of a patient is concave along at least one axis prior to manipulation of the implantable medical device, and wherein the surface of the overmold is concave such that the overmold conforms substantially to an arc, and a radius of the arc is within a range from 4.5 to 9.5 centimeters.

As described previously with respect to Applicant's claims 1 and 28, Leysieffer fails to disclose or suggest a plurality of modules, each with a metallic housing. In support of the rejection of claim 1, which is similar to Applicant's claim 30, the Examiner incorrectly asserted that each one of modules 20 comprises a module and housing. Modules 20 of Leysieffer contain two legs of material having different electrical conductivity, both thermally coupled to hot pole 15 at one end and cold pole 16 at an opposite end. The legs, which serve to create an electrical output, may be composed of titanium and are connected to each other by thermally insulating composite element 23.[4] Leysieffer fails to disclose or suggest that modules 20 each comprise a housing, or that they house anything. Instead, Leysieffer's disclosure suggests that each module is merely composed of semiconductive material without any other housing.

In support of the rejection of claim 28, which is similar to Applicant's claim 30, the Examiner cited column 4, lines 26-41 of Leysieffer as teaching that the housings of modules 20 may comprise metals. However, this passage describes that legs 21 and 22 of a module may be made of metals such as titanium and titanium alloys. Leysieffer does not disclose or suggest that

[4] Leysieffer, column 4, lines 4-41.

modules 20 each comprise a housing and certainly does not disclose or suggest that the legs of a module comprise a housing. For at least these reasons, Leysieffer does not disclose or suggest a plurality of modules, each with a metallic housing. Claim 31 is dependent upon claim 30 and is also in condition for allowance.

Applicant's amended claim 23, recites "an implantable medical device comprising a metallic housing that includes an outer surface that is adapted to be implanted on a cranium of a patient, wherein the surface is concave along at least two axes such that the surface conforms substantially to an arc, and a radius of the arc is within a range from 4.5 to 9.5 centimeters.

In support of the rejection, the Examiner cited Muto as teaching the requirements of claim 23. As amended, claim 23 requires that an outer surface that is adapted to be implanted on a cranium of a patient is concave along at least two axes. Muto describes a pacemaker casing formed by a substantially flat, planar bottom and a shallow domed top.[5] The top outer surface of Muto is convex rather than concave. Additionally, the pacemaker described by Muto is adapted to be implanted in the chest region of a patient, not on a cranium of a patient. Muto fails to disclose or suggest the requirements of Applicant's amended claim 23. Claim 24, 26 and 27 are dependent upon claim 23 and are also in condition for allowance.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 7-9, 19-21, 23-24, 26-27 and 30-31 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

[5] Muto, column 2, lines 53-56 and FIG. 1.

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**Rejection for Obviousness-type Double Patenting**

The Examiner provisionally rejected claims 1-24 and 26-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21, 22-37, 39, 40, 42-53 and 55 (amended on November 28, 2005) of copending Application No. 10/731,869; claims 1-24 and 26-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 15-17 and 22-23 (amended on May 24, 2006) of copending Application No. 10/731,868; claims 1-24 and 26-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 (amended on November 16, 2005) of copending Application No. 10/731,638; and claims 1-24 and 26-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 (amended on June 16, 2006) of copending Application No. 10/730,873.

Applicants note the provisional status of these rejections. Accordingly, Applicants will address these issues if and when the rejections are formally applied.

**New Claims**

Applicant has added claims 32 and 33 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the applied references fail to disclose or suggest control circuitry within the housing of one of the modules, wherein the control circuitry at least one of delivers a therapy to a patient or monitors a patient, as required by claim 32. Additionally, the applied references fail to disclose or suggest power source located the housing of one of the modules, as required by Applicant's claim 33. No new matter has been added by the new claims.

## CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: November 3, 2006

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